

REMARKS

After entry of this amendment, claims 1-34 are pending, of which claims 12-34 are withdrawn. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Claims 3 and 4 find further support in the specification, for example, at page 75, lines 8-27. No new matter has been added.

Upon allowance of the generic claim, claim 1, or the claims directed to the elected species, Applicants respectfully request rejoinder of the non-elected species. 37 CFR § 1.141; MPEP § 809.02(a).

Claim Objections

Claims 1 and 2 are objected to for reciting non-elected subject matter, i.e. $\Delta 9$ -elongase and $\Delta 8$ -desaturase. In response, claims 1 and 2 have been amended without prejudice or disclaimer to delete the non-elected subject matter. It is believed that the present amendment overcome the objection. Reconsideration and withdrawal of the objection is respectfully requested.

Claims 2-4 are objected to for reciting non-elected sequences. In response, claim 2 has been amended to delete the sequences that correspond to the non-elected subject matter, i.e. $\Delta 9$ -elongase and $\Delta 8$ -desaturase. Applicants note that, as confirmed by the Examiner in the Office Action at page 2, the election to the sequences that correspond to the elected subject matter is for search purposes only, i.e. species election. Accordingly, upon allowance of the generic claim or the claims directed to the elected species, Applicants respectfully request rejoinder of the non-elected species. 37 CFR § 1.141; MPEP § 809.02(a). In light of the present amendment and the above remarks, reconsideration and withdrawal of the objection is respectfully requested.

Specification

The specification is objected to as being unclear as to whether it contains a brief description of the drawings. The specification is further objected to for not containing the preferred headings for each section as suggested in the MPEP. In response, the specification has

been amended to include the appropriate section headings as suggested in the MPEP. Additionally, a section entitled "BRIEF DESCRIPTION OF THE DRAWINGS" has been inserted at page 6 to accommodate the figure legends found on top of each drawing. Support is found *inter alia* in the drawings containing Figures 1-30. Further support for the brief description of Figure 23 is found in the specification, for example, at page 121, lines 1-2. No new matter has been added. In view of the present amendments, reconsideration and withdrawal of the objection is respectfully requested.

Double Patenting

Claim 3 is provisionally rejected for obviousness-type double patenting over claims 1-9 of co-pending Application No. 10/590,958. Because this is a provisional double patenting rejection, Applicants will consider filing an appropriate terminal disclaimer upon an indication that the claims are allowable.

Claim Rejection – 35 U.S.C. § 102

Claims 1 and 5-11 are rejected under 35 USC § 102(b) as being anticipated by Drexler *et al.* (hereinafter "Drexler").

The Examiner contends that Drexler teaches a process to produce compounds of Formula I in a plant by introducing into the plant coding sequences for a $\Delta 6$ -elongase, a $\Delta 6$ -desaturase, a $\Delta 5$ -desaturase, a $\Delta 5$ -elongase, and a $\Delta 4$ -desaturase. The Examiner asserts that the biosynthetic pathway is known and genes for these enzymes are cloned from numerous eukaryotic organisms and bacteria. The Examiner further alleges that Drexler teaches transformation of canola with desaturase coding sequences to produce polyunsaturated fatty acid (18:3). The Examiner additionally argues that the recited substituents of R2 and R3, as well as the percentage of Formula I compounds produced, would be inherent in the same process. Applicants strongly disagree and traverse the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "Rejections under 35 U.S.C. § 102 are

proper only when the claimed subject matter is identically disclosed or described in the prior art. Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. The prior art reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008) (holding “that unless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”).

As acknowledged by the Examiner, Drexler provides a general review of biosynthesis of arachidonic acid (“ARA”), eicosapentaenoic acid (“EPA”), and docosahexaenoic acid (“DHA”), as summarized in Figure 6 at page 795. However, contrary to the Examiner’s assertion, Drexler does not teach production of very long-chain polyunsaturated fatty acids (“VLCPUFA”) by introducing into one single plant nucleotide sequences encoding a $\Delta 6$ -desaturase, a $\Delta 6$ -elongase, a $\Delta 5$ -desaturase, a $\Delta 5$ -elongase, and a $\Delta 4$ -desaturase. The lack of such teaching is further evidenced from the statement found at page 796 of Drexler, where it states, “[t]he only enzyme which has not yet been identified by explicit functional expression studies of the isolated cDNA is a $\Delta 5$ -specific elongase limited to the elongation of C20- to C22-fatty acids and that does not initiate the several elongation cycles as typical for a mammalian enzyme.” Drexler at page 796, left Col., lines 10-15. Because one of the enzymes required to practice the alleged process has not yet been identified, it is clear that Drexler does not teach each and every limitation as set forth in the claims, either expressly or inherently, within its four corners. Accordingly, Drexler does not anticipate the claims. For at least this reason, the rejection should be withdrawn.

Moreover, Applicants respectfully submit that Drexler does not enable one skilled in the art to make the claimed subject matter without undue experimentation and thus, does not anticipate the claims. To anticipate, a prior art reference must be enabling, *i.e.* it must “enable

one of ordinary skill in the art to make the invention without undue experimentation.” *See Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1379 (Fed. Cir. 2007)).

Here, as stated in Drexler at page 796, difficulties still exist in coexpressing several cDNAs for VLCPUFA production in plants. For instance, one of such difficulties is how to avoid the formation of fatty acid isomers. See Drexler at page 796, paragraph bridging left and right Cols (“[d]espite the fact that several cDNAs have to be coexpressed for VLCPUFA biosynthesis, these approaches are conceptually at the level of the single gene constructs Most important will be the selection of cDNAs encoding enzymes of the highest selectivity to avoid the formation of fatty acid isomers”). However, Drexler does not provide any teaching to solve such difficulties. For example, no information of enzymes that can be used for the production of VLCPUFA in plants to avoid the aforementioned formation of fatty acid isomers is provided in Drexler. With this regarding, Applicants note that, as stated in Drexler at page 781, this reference provides only an overview of some existing strategies and projects regarding the current and future aspects of the changes in fatty acid profiles in plant seed oils. Drexler, page 781, right Col., last paragraph. Thus, it is clear that, while summarizing the state of the art in metabolic engineering of fatty acid production in plant, Drexler does not provide any solution to the problems encountered by the existing methods. Accordingly, Drexler does not enable one skilled in the art to make the claimed subject matter without undue experimentation. For this additional reason, Drexler does not anticipate the claims and the rejection should be withdrawn.

For at least the above reasons, Applicants submit that Drexler does not anticipate the claimed subject matter. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. § 103(a) as being obvious over Drexler in view of Geneseq Accession No. ABV74260.

The Examiner's reliance on Drexler is the same as discussed above in the anticipation rejection. Specifically, the Examiner asserts that Drexler teaches a process to produce compounds of Formula I in a plant by introducing into the plant coding sequences for a $\Delta 6$ -elongase, a $\Delta 6$ -desaturase, a $\Delta 5$ -desaturase, a $\Delta 5$ -elongase, and a $\Delta 4$ -desaturase. The Examiner acknowledges that Drexler does not teach the $\Delta 6$ -desaturase of SEQ ID NO: 23, but relied on ABV74260 for such teaching. Based on the above assertions, the Examiner contends that one skilled in the art would have been motivated to substitute the enzyme coding sequences used in Drexler's method with other known sequences such as that of ABV74260. The Examiner further asserts that the particular R2 and R3 constituents and levels of PUFAs would be the optimization of process parameters. The Examiner thus concludes that the claimed process would have been obvious absent evidence to the contrary. Applicants respectfully disagree.

The Examiner bears the initial burden of establishing *prima facie* obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. *See In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The discussion above concerning Drexler is equally applicable here and thus, is incorporated by reference in its entirety. As discussed above, Drexler does not teach production of VLCPUFA by introducing into one single plant nucleotide sequences encoding a $\Delta 6$ -desaturase, a $\Delta 6$ -elongase, a $\Delta 5$ -desaturase, a $\Delta 5$ -elongase, and a $\Delta 4$ -desaturase. Particularly, as noted by Drexler, $\Delta 5$ -specific elongase has not yet identified at the time. Moreover, as also discussed above, Drexler provides only an overview of existing strategies and projects used in the production of fatty acids in plants, including the problems encountered by those strategies and projects. Drexler, however, does not provide any solution to those problems. Thus, Drexler does not enable one skilled in the art to practice the process to produce compounds of Formula I in a plant as alleged by the Examiner.

The combination of Drexler with ABV74260 does not remedy this deficiency. As noted by the Examiner, ABV74260 discloses a $\Delta 6$ -desaturase coding sequence from *Physcomitrella patens*. Drexler and ABV74260, even if combined, still do not teach or suggest a $\Delta 5$ -specific

elongase coding sequence, which, according to Drexler, has not yet been identified. Moreover, it is noted that ABV74260 provides only the sequence information of a $\Delta 6$ -desaturase but not any solution to the problems encountered by the prior art strategies and projects as summarized in Drexler. Thus, even if combined, Drexler and ABV74260 still do not enable one skilled in the art to practice the process that is allegedly taught in Drexler.

Because Drexler and ABV74260, alone or in combination, do not teach or suggest all the limitations of the claimed process, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 4 is rejected under 35 U.S.C. § 103(a) as being obvious over Drexler in view of Geneseq Accession No. ABV74262. The Examiner's reliance on Drexler is the same as discussed above. The Examiner further relies on ABV74262 for allegedly teaching a sequence that is 62.9% identical to SEQ ID NO: 110. Applicants strongly disagree. However, to expedite prosecution, claim 4 has been amended without prejudice or disclaimer to recite the claimed subject matter with more specificity. In light of the present amendment, it is believed that the rejection is rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 3 is rejected under 35 U.S.C. § 103(a) as being obvious over Drexler in view of EST Accession No. BE777235. The Examiner's reliance on Drexler is the same as discussed above. The Examiner further relies on BE777235 for allegedly teaching a sequence that is 60% identical to SEQ ID NO: 88. Applicants disagree. However, to expedite prosecution, claim 3 has been amended without prejudice or disclaimer to recite the claimed subject matter with more specificity. In light of the present amendment, it is believed that the rejection is rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.

This response is filed within the three-month period for response from the mailing of the Office Communication to and including February 25, 2010. No fee is believed due. However, if a fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00193-US from which the undersigned is authorized to draw.

Respectfully submitted,

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